

REMARKS

This is a response to the final Office Action mailed on November 16, 2010. A Petition for a three month extension of time and request for continued examination ("RCE") is submitted herewith this response. The Director is authorized to charge the Petition for a three month extension of time and the RCE and any additional fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036-753 on the account statement.

Claims 1-8, 12-14 and 20-21 are rejected in this application. Claims 9-11 and 15-19 were previously withdrawn and are now canceled without disclaimer. In the Office Action, Claims 1-8, 12-14 and 20-21 are rejected under 35 U.S.C. §103. In response, Claim 1-8, 12-14 and 20-21 have been amended, and Claims 22-28 have been added. The amendments do not add new matter. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

Claims 1-8, 12-14 and 20-21 have been amended, in part, for clarification purposes.

In the Office Action, Claims 1-8, 12-14 and 20-21 are rejected under 35 U.S.C. §103(a) as being obvious over JP 09107880 to Osanai ("*Osanai*"), in view of Journal of Agricultural and Food Chemistry to Edenharter et al. ("*Edenharter*"), Eur J. Nutr to Faulks et al. ("*Faulks*") and Royal Society of Chemistry to Hovari et al. ("*Hovari*") and further in view of JP 2003164261 to Imazawa et al. ("*Imazawa*"). Applicants respectfully traverse the rejection for at least the reasons set forth below.

Independent Claims 1, 12 and 14 have been amended to recite, in part, that the miscible primary composition is stable, miscible and dispersible in an aqueous system. The amendments are supported in the specification, for example, at page 2, lines 22-28 and page 3, lines 6-11. Independent Claim 12 has also been amended to recite, in part, a freeze-dried, miscible powder comprising at least essential lipophilic and hydrophilic bioactive components of a material selected from the group consisting of whole fruit, vegetable material, plant material, and combinations thereof, excluding insoluble fibers, in a milk or milk protein-containing carrier. The amendment is supported in the specification, for example, at page 3, lines 19-29, and Examples 1-2.

Conventional techniques for extracting such bioactive components only extract some of the bioactive components from the fruit or plant material. Water extraction techniques, in which

the bioactive components are extracted from insoluble fibers, preserve the natural image and nutritional functions of the bioactive components but are not very efficient. Solvent extraction techniques, while more efficient than water extraction, still fail to extract a substantial portion of the bioactive components from the fruit or plant material and simultaneously impair the nutritional functions of the bioactive components. See specification, page 1, line 23-page 2, line 28. Therefore, traditional water and solvent extraction techniques are only able to extract a few compounds of the fruit or plant material, leaving some other bioactive materials in the remaining material. For example, polysaccharides, polyphenols and other non-lipophilic compounds are not extracted together with the lipophilic components such as carotenoids, lipophilic vitamins and other lipids.

The claimed compositions are produced by processes that allow for the extraction of a greater amount of bioactive materials than with traditional water or solvent extraction techniques. The fruit or plant material is mixed in a milk or milk protein-containing medium and separated from insoluble fibers to obtain an aqueous suspension. By using a milk or milk protein-containing carrier to extract the bioactive components from the fruit or plant material and centrifuging the milk or milk protein-containing carrier, the present claims provide compositions having bioactive components with improved miscibility, stability and bioavailability over conventional extraction techniques without the use of organic solvent residues. See specification, page 3, lines 19-page 4, line 10; page 7, lines 5-12. By using milk or milk proteins, soy-milk or milk-like proteins from plants, the claimed compositions provide a similar profile of the important nutrients like the whole fruit.

Applicants have surprisingly found that milling the material contained in the milk or milk protein-containing carrier allows for the formation of much smaller particles of ground plant material, allowing more efficient access by the milk or milk protein-containing carrier to both the water-soluble and oil-soluble bioactives of the plant material. Moreover, Applicants have found that the proteins in the milk or milk protein-containing carrier are significant for the increased extraction of the lipophilic and hydrophilic bioactive components from the plant material. Furthermore, centrifuging the milk or milk protein-containing carrier after milling of the fruit or plant materials removes the insoluble fibers and further provides the claimed composition as a whole to be stable, miscible and dispersible in an aqueous system. See specification, page 2, lines 22-28 and page 3, lines 6-11.

Osanai, Edenharder, Faulks, Hovari and *Imazawa* fail to disclose or suggest each and every element of independent Claims 1, 12 and 14. *Osanai, Edenharder, Faulks, Hovari* and *Imazawa* alone or in combination fail to disclose or suggest a miscible primary composition comprising a milk-based carrier that is stable, miscible and dispersible in an aqueous system as required by independent Claims 1, 12 and 14. *Osanai, Edenharder, Faulks, Hovari* and *Imazawa* also fail to a freeze-dried, miscible powder comprising essential lipophilic and hydrophilic bioactive components of a material from whole fruit, vegetable material and/or plant material, excluding insoluble fibers, in a milk or milk protein-containing carrier as required by independent Claim 12.

Osanai discloses a beverage containing cow's milk, rapa gourd, spinach and lemon, among other ingredients. See *Osanai*, pages 5-6. To distinguish the composition of *Osanai* with that of the claimed compositions, Applicants submit herewith a Declaration under 37 C.F.R. §1.132 ("*Declaration*") that demonstrates the deficiencies of the prior art with respect to the present claims.

As supported by the *Declaration*, *Osanai* discloses a beverage containing cow's milk, rapa gourd, spinach and lemon, among other ingredients. Each of the embodiments of the beverage disclosed by *Osanai* at least includes approximately 22.5 grams of lemon. Moreover, lemon is an essential aspect of *Osanai's* beverage as it supplies vitamin C in an amount that is not satisfied with the remaining elements of the beverage. See *Osanai*, paragraph 12.

As supported by the *Declaration*, an experiment was performed to determine the impact of lemon on cow's milk as taught by *Osanai*. The experiment showed that the addition of 22.5 grams of lemon to 100 ml of milk led to a precipitation/coagulation of a large portion of the milk proteins in the milk causing an obvious lack of miscibility. See Exhibit A of the *Declaration*. Therefore, upon experimental testing to compare *Osanai's* beverage against the claimed invention, it is clear that *Osanai* does not provide a miscible primary composition that is stable, miscible and dispersible in an aqueous system according to the claimed invention.

As supported by the *Declaration*, the inventors have surprisingly found that the milk proteins are essential for the improved extraction of the lipophilic bioactive components according to the claimed invention. The claimed miscible primary composition comprising a milk-based carrier that is stable, miscible and dispersible in an aqueous system provides the optimal conditions for extracting the most lipophilic bioactive components from plant materials.

In contrast, because of the precipitation/coagulation of a large portion of the milk proteins in the beverage of *Osanai*, these precipitated or coagulated proteins are immiscible in solution and are no longer free to extract the lipophilic bioactive components of plant materials. This reduces the effectiveness of the extraction and the amount of the extracted bioactive components that could end up in the beverage. As a result, the miscible primary composition of the claimed invention is a distinguishable product over the immiscible beverage resulting from the components and process of *Osanai*.

Applicants also respectfully submit that the skilled artisan would have no reason to combine the cited references to arrive at the present claims because the cited references are directed to unrelated products that have completely different objectives. *Osanai* is entirely directed to cow's milk containing vegetables whose main constituent is rapa gourd, wherein the vegetable containing rapa gourd is mixed with cowsmilk. See *Osanai*, pages 5-6. *Edenharder* is entirely directed to the isolation and characterization of antimutagenic flavonoids from spinach. See *Edenharder*, Abstract. Indeed, the entire disclosure of *Edenharder* is directed to the purification of antimutagens from spinach by preparative and micropreparative HPLC from a methanol/water extract of dry spinach after removal of lipophilic compounds. *Id.* As such, not only is the subject matter of *Edenharder* nonanalogous art when compared to *Osanai* and the present claims, but *Edenharder* teaches away from the present claims when *Edenharder* discloses removal of lipophilic compounds from the spinach extract.

Similar to *Edenharder*, *Faulks* is entirely directed to the quantification of β -carotene and lutein absorption from a representative green vegetable with different degrees of processing, using both mass balance and metabolic modeling of triglyceride-rich lipoprotein plasma fraction. See *Faulks*, Summary. Like *Edenharder*, the green vegetable of *Faulks* is spinach and the entire disclosure is directed to the kinetics of gastro-intestinal transit and carotenoid absorption and disposal in ileostomy volunteers fed spinach meals. See *Faulks*, Summary and Introduction. As such, *Faulks* is also nonanalogous art when compared to *Osanai* and the present claims.

Hovari is entirely directed to the effects of flavanoids on human health and the content of flavonoids in specific vegetables. See *Hovari*, Introduction, Table 1. *Imazawa* is entirely directed to extraction efficiency and preparation of juice in a short time for industrialization. See *Imazawa*, paragraphs 18 and 19. *Imazawa* discloses processes that include pulverizing coffee

beans, fruits, vegetables, etc., adding a dispersing media to the pulverized coffee beans, fruits, vegetables, etc., and then homogenizing the mixture. See *Imazawa*, Working Examples.

As such, the cited references are clearly directed to unrelated products or processes that have completely different objectives. Moreover, none of the cited references even recognizes the benefits obtained by the presently claimed compositions including, for example, improved bioavailability and miscibility of from extracted fruits or plant materials by milling the material in a milk or milk protein-containing carrier and centrifuging the milk or milk protein-containing carrier after milling of the fruit or plant materials to remove the insoluble fibers. Such treatments allow the essential lipophilic and hydrophilic bioactive components to have improved bioavailability and miscibility in the milk or milk protein-containing carrier. See specification, page 4, lines 1-3.

Finally, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there exists no reason for the skilled artisan to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). In fact, Applicants submit that what the Patent Office has done here is to apply hindsight reasoning by attempting to selectively piece together teachings of each of the references in an attempt to recreate what the claimed invention discloses. Indeed, the skilled artisan must have a reason to combine the cited references to arrive at the present claims. Applicants respectfully submit that such a reason is not present in the instant case.

For at least the reasons discussed above, the cited references fail to disclose or suggest each and every element of independent Claims 1, 12 and 14. Moreover, the cited references fail to even recognize the advantages, unexpected benefits and/or properties of a miscible primary composition that is stable, miscible and dispersible in an aqueous system in accordance with the present claims. As a result, Applicants respectfully submit that independent Claims 1, 12 and 14, along with any claims that depend from Claims 1, 12 and 14, are novel, nonobvious and distinguishable from the cited references.

Accordingly, Accordingly, Applicants respectfully request that the rejection of Claims 1-8, 12-14 and 20-21 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

Applicants further note that Claims 22-28 have been newly added. The new claims are fully supported in the specification, for example, at page 2, lines 22-28, page 3, lines 6-11, and page 6, lines 27-31. Applicants respectfully submit that Claims 22-28 should be allowed for at

least the reasons set forth above. In addition, the cited references fail to disclose or suggest a miscible primary composition comprising a plant-based milk carrier that is stable, miscible and dispersible in an aqueous system as required by independent Claim 22.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly request an early allowance of the same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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